Complete Summary

GUIDELINE TITLE

Celiac disease (CD). Evidence-based nutrition practice guideline.

BIBLIOGRAPHIC SOURCE(S)

American Dietetic Association (ADA). Celiac disease (CD). Evidence based nutrition practice guideline. Chicago (IL): American Dietetic Association (ADA); 2009. Various p. [341 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Celiac disease

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Counseling
Diagnosis
Evaluation
Management
Screening
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Critical Care
Endocrinology
Family Practice
Gastroenterology
Hematology
Neurology
Nutrition
Obstetrics and Gynecology
Pediatrics
Rheumatology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Nurses
Pharmacists
Physician Assistants
Physicians
Social Workers
Students

GUIDELINE OBJECTIVE(S)

Overall Objective

To provide medical nutrition therapy (MNT) guidelines for celiac disease to promote optimal health, prevent and treat malabsorption/malnutrition and other comorbidities, and improve quality of life

Specific Objectives

- To define evidence-based celiac disease nutrition recommendations for registered dietitians (RDs) that are carried out in collaboration with other healthcare providers
- To guide practice decisions that integrate medical, nutritional and behavioral strategies
- To achieve consistency in practice among RDs
- To provide the RD with data to make recommendations to adjust MNT or recommend other therapies to achieve desired outcomes
- To enhance the quality of life for the individual with celiac disease, utilizing customized strategies based on the individual´s preferences, lifestyle and goals
- To develop guidelines for interventions that have measurable clinical outcomes
- To define the highest quality of care within cost constraints of the current healthcare environment

TARGET POPULATION

Infants (1-23 months), preschool children (2-5 years), children (6-12 years), adolescents (13-18 years), adults (19-79 years) with celiac disease

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

1. Referral to a registered dietitian
2. Nutrition assessment
    - Client history including medical, social and personal history and history of medications and supplements
    - Biochemical data and relevant laboratory values
    - Anthropometric measurements including height, weight, body mass index (BMI), and weight change rate
    - Nutrition history including food intake, physical activity and exercise, food availability, psychosocial and economic issues impacting nutrition therapy,Â and consideration of co-morbid conditions
    - Physical examination findings

Management/Treatment

1. Individualized prescription based on:
    - Nutrition intervention such as inclusion of gluten-free oats,Â whole or enriched gluten-free grains, multivitamin and mineral supplements, calcium and vitamin D, iron supplementation; patient education on label reading and food cross-contamination
    - Physical activity interventions
    - Behavioral interventions
    - Pharmacotherapy, when indicated
2. Coordination of nutrition care
3. Monitoring of progress

MAJOR OUTCOMES CONSIDERED

- Bone density
- Iron deficiency anemia
- Villous atrophy
- Gastrointestinal and neurological symptoms
- Pregnancy outcomes
- Dietary compliance
- Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches of PubMed and hand searches of other relevant literature were performed on the following topics:

- Medical nutrition therapy and dietitian intervention
- Gluten-free dietary pattern
- Inclusion of oats in the dietary pattern
- Quality of life
- Education

General Exclusion Criteria

As a general rule, studies are excluded if the:

- Study sample size is less than 10 in each treatment group
- Drop-out rate was >20%

Inclusion Criteria

- Study design preferences: randomized controlled trials, clinical controlled studies, large nonrandomized observational studies, cohort and case-control studies
- Limited to articles in English

The American Dietetic Association (ADA) has determined that for narrowly focused questions dealing with therapy or treatment, six well designed randomized controlled trials that demonstrate similar results is sufficient to draw a conclusion.

No one study design was preferred for all questions. The preferred study design depended on the type of question. The ADA uses the following principles in the table below for identifying preferred study design.

Type of Question	Preferred Study Designs (in Order of Preference)
Diagnosis questions	Sensitivity & specificity of diagnostic test Cross-sectional study
Etiology, causation, or harm questions	Prospective cohort Case control study Cross-sectional study
Therapy and prevention questions	Randomized controlled trial Nonrandomized trial
Natural history and prognosis questions	Cohort study

NUMBER OF SOURCE DOCUMENTS

171 considered

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Grading the Strength of the Evidence for a Conclusion Statement or Recommendation Conclusion Grading Table

Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert Opinion Only	Grade Grade Assigna
Quality • Scientific rigor/validity • Considers design and execution	Studies of strong design for question Free from design flaws, bias and execution problems	Studies of strong design for question with minor methodological concerns OR Only studies of weaker study design for question	Studies of weak design for answering the question OR Inconclusive findings due to design flaws, bias or execution problems	No studies available Conclusion based on usual practice, expert consensus, clinical experience, opinion, or extrapolation from basic research	No evidence that pertains question being address
Consistency Of findings across studies	Findings generally consistent in direction and size of effect or degree of association, and statistical significance with minor exceptions at most	Inconsistency among results of studies with strong design OR Consistency with minor exceptions across studies of weaker designs	Unexplained inconsistency among results from different studies OR Single study unconfirmed by other studies	Conclusion supported solely by statements of informed nutrition or medical commentators	NA
Quantity • Number of	One to several good quality studies	Several studies by independent	Limited number of studies	Unsubstantiated by published studies	Relevan studies have no

Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert Opinion Only	Grade Grade Assigna
• studies • Number of subjects in studies	Large number of subjects studies Studies with negative results having sufficiently large sample size for adequate statistical power	investigators Doubts about adequacy of sample size to avoid Type I and Type II error	Low number of subjects studies and/or inadequate sample size within studies		been do
Clinical Impact • Importance of studied outcomes • Magnitude of effect	Studied outcome relates directly to the question Size of effect is clinically meaningful Significant (statistical) difference is large	Some doubt about the statistical or clinical significance of effect	Studies outcome is an intermediate outcome or surrogate for the true outcome of interest OR Size of effect is small or lacks statistical and/or clinical significance	Objective data unavailable	Indicate area for future research
Generalizability To population of interest	Studied population, intervention and outcomes are free from serious doubts about generalizability	Minor doubts about generalizability	Serious doubts about generalizability due to narrow or different study population, intervention or outcomes studied	Generalizability limited to scope of experience	NA

This grading system was based on the grading system from: *Greer N, Mosser G, Logan G, Wagstrom Halaas G. A practical approach to evidence grading. Jt Comm. J Qual Improv. 2000; 26:700-712*. In September 2004, The ADA Research Committee modified the grading system to this current version.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Step One: Formulate the question

Specify a question in a defined area of practice; or state a tentative conclusion or recommendation that is being considered. Formulate questions using PICO format which includes population, intervention, comparison, and outcomes of interest. Determine inclusion and exclusion criteria.

Step Two: Gather and classify evidence reports

Conduct a systematic search of the literature in electronic databases to find evidence related to the question, gather studies and reports, and classify them by type of evidence. Classes differentiate primary reports of new data according to study design, and distinguish them from reports that are a systematic review and synthesis of primary reports.

Step Three: Critically appraise each report

Review each report for relevance to the question and critique for scientific validity. Abstract key information from the report and document. Assign a code to indicate the quality of the study by completing quality criteria checklist.

Step Four: Summarize evidence in aÂ narrative and an overview table

Combine findings from all reports in a table that pulls out the important information from the article worksheets. Write a brief narrative that summarizes and synthesizes the information abstracted from the articles that is related to the question asked.

Step Five: Develop a conclusion statement and grade the strength of evidence supporting the conclusion

Develop a concise conclusion statement (the answer to the question), taking into account the synthesis of all relevant studies and reports, their class and their quality ratings. Assign a grade to indicate the overall strength or weakness of evidence informing the conclusion statement.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The expert workgroup, which includes practitioners and researchers with a depth of experience in the specific field of interest, develops the disease-specific guideline. The guideline development involves the following steps.

Review the Conclusion Statements

The workgroup meets to review the materials resulting from the evidence analysis, which may include review of the conclusion statements, evidence summaries and evidence worksheets.

Formulate Recommendations for the Guideline Integrating Conclusions from Evidence Analysis

The workgroup uses an expert consensus method to formulate the guideline recommendations and complete the various sections on the recommendation page. These include:

- Recommendations for what the dietitian should do and why
- Rating of recommendations based on strength of supporting evidence
- Label of Conditional (clearly define a specific situation) or Imperative (broadly applicable to the target population without restraints on the pertinence)
- Risks and Harms of Implementing the Recommendations, including potential risks, harms, or adverse consequences
- Conditions of Application, including organizational barriers or conditions that may limit application
- Potential Costs Associated with Application
- Recommendation Narrative
- Recommendation Strength Rationale, evidence strength and methodological issues
- Minority Opinions, when the expert working group cannot reach consensus on a recommendation
- Supporting Evidence

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Criteria for Recommendation Rating

Statement Rating	Definition	Implication for Practice
Strong	A **Strong** recommendation means that the workgroup believes that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation), and that the quality of the supporting evidence is excellent/good (grade I or II)*. In some clearly identified circumstances, strong	Practitioners should follow a **Strong** recommendation unless a clear and compelling rationale for an alternative approach is present.

Statement Rating	Definition	Implication for Practice
	recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	
Fair	A **Fair** recommendation means that the workgroup believes that the benefits exceed the harms (or that the harms clearly exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade II or III)*. In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Practitioners should generally follow a **Fair** recommendation but remain alert to new information and be sensitive to patient preferences.
Weak	A **Weak** recommendation means that the quality of evidence that exists is suspect or that well-done studies (grade I, II, or III)* show little clear advantage to one approach versus another.	Practitioners should be cautious in deciding whether to follow a recommendation classified as **Weak**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.
Consensus	A **Consensus** recommendation means that Expert opinion (grade IV)* supports the guideline recommendation even though the available scientific evidence did not present consistent results, or controlled trials were lacking.	Practitioners should be flexible in deciding whether to follow a recommendation classified **Consensus**, although they may set boundaries on alternatives. Patient preference should have a substantial influencing role.
Insufficient Evidence	An **Insufficient Evidence** recommendation means that there is both a lack of pertinent evidence (grade V)* and/or an unclear balance between benefits and harms.	Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Insufficient Evidence** and should exercise judgment and be alert to emerging publications that report evidence that clarifies the balance of benefit versus harm. Patient preference should have a substantial influencing role.

*Conclusion statements are assigned a grade based on the strength of the evidence. Grade I is good; grade II, fair; grade III, limited; grade IV signifies expert opinion only and grade V indicates that a grade is not assignable because there is no evidence to support or refute the conclusion. The evidence and these grades are considered when assigning a rating (Strong, Fair, Weak, Consensus, Insufficient Evidence - see chart above) to a recommendation.

Adapted by the American Dietetic Association from the American Academy of Pediatrics, Classifying Recommendations for Clinical Practice Guideline, Pediatrics. 2004;114;874-877.

COST ANALYSIS

An analysis was performed of potential costs associated with application of the recommendations in the guideline.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Each guideline is reviewed internally and externally using the AGREE (Appraisal of Guidelines for Research and Evaluation) instrument as the evaluation tool. The external reviewers consist of a multidisciplinary group of individuals (may include dietitians, doctors, psychologists, pharmacists, nurses, etc.). The review is done electronically. The guideline is adjusted by consensus of the expert panel and approved by American Dietetic Association's Evidence-Based Practice Committee prior to publication on the Evidence Analysis Library (EAL).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Ratings for the strength of the recommendations (Strong, Fair, Weak, Consensus, Insufficient Evidence), conclusion grades (I-V), and statement labels (Conditional versus Imperative) are defined at the end of the "Major Recommendations" field.

Celiac Disease (CD) Medical Nutrition Therapy

CD: Medical Nutrition Therapy

Medical nutrition therapy (MNT) provided by a registered dietitian (RD) is strongly recommended for individuals with CD. Consultation with a RD as part of a team-based approach results in improved self-management.

Consensus, Imperative

Recommendation Strength Rationale

- The American Dietetic Association (ADA) Celiac Disease Work Group concurs with the National Institutes of Health Consensus Development Conference Statement.

CD Assessment of Food/Nutrition-Related History

CD: Assessment of Food/Nutrition-Related History

The RD should assess the food and nutrition-related history of individuals with CD, including (but not limited to) the following:

- Food and nutrient intake (e.g., diet history, diet experience and macronutrient or micronutrient intake, specifically calcium, iron, vitamin B complex and vitamin D)
- Medication and herbal supplement use
- Knowledge, beliefs or attitudes (e.g., readiness to change nutrition-related behaviors)
- Behavior (e.g., social network)
- Factors affecting access to food and food and nutrition-related supplies (e.g., safe food and meal availability)

Assessment of the above factors is needed to effectively determine nutrition diagnoses and plan the nutrition intervention. Intake of gluten results may result in gastrointestinal symptoms, malabsorption and villous atrophy.

Strong, Imperative

Recommendation Strength Rationale

- Conclusion statementsÂ were **Grade II**

CD Assessment of Factors Affecting Quality of Life

CD: Assess Factors Affecting Quality of Life

The RD should assess the factors affecting the quality of life of individuals with CD when completing a comprehensive client history, which includes a medical history (e.g., gastrointestinal, immune, neurological and psychological) and social history (e.g., socioeconomic factors, religion, social and medical support and daily stress level). Individuals with CD may not attain the same level of quality of life as the general population, due to social inconveniences of following a gluten-free dietary pattern.

Strong, Imperative

Recommendation Strength Rationale

- Conclusion statementsÂ were **Grades I and II**

CD Bone Density Screening

CD: Bone Density Screening

The RD should recommend bone density screening for adults with CD within the first year. Clinical trials and cross-sectional studies have reported reduced bone mineral content and bone mineral density in untreated adults with CD.

Strong, Conditional

Recommendation Strength Rationale

- Conclusion statementÂ was **Grade I**

CD Assess Biochemical Data and Results of Medical Procedures

CD: Assess Biochemical Data and Results of Medical Procedures

The RD should assess the biochemical data and review the results of medical procedures in individuals with CD, regardless of presentation and clinical symptoms, including (but not limited to) the following:

- Gastrointestinal profile (e.g., intestinal biopsy [or skin biopsy in the case of dermatitis herpetiformis] and celiac antibodies)
- Nutritional anemia profile (e.g., folate, ferritin and vitamin B12)
- Vitamin profile (e.g., thiamin, vitamin B6 and 25-hydroxy vitamin D)
- Mineral profile (e.g., copper and zinc)
- Lipid profile
- Electrolyte and renal profile

Untreated CD results in villous atrophy and malabsorption. The use of effective techniques to assess nutritional status is essential to prevention and treatment of malnutrition and the presence of iron deficiency anemia.

Strong, Imperative

Recommendation Strength Rationale

- Conclusion statementsÂ were **Grade II**

CD Assessment of Gastrointestinal Symptoms

CD: Assess Gastrointestinal Symptoms

The RD should assess gastrointestinal symptoms (such as type, frequency and volume of bowel function; abdominal pain and bloating; nausea or vomiting; reduced gut motility and delayed gastric emptying) in individuals with CD. Several studies have reported that people with CD (treated and untreated) are more likely to experience gastrointestinal symptoms than are healthy control subjects.

Strong, Imperative

Recommendation Strength Rationale

- Conclusion statementÂ was **Grade II**

CD Assessment of Other Disease States

CD: Assessment of Other Disease States

The RD should assess for the presence of other disease states, such as thyroid conditions, other autoimmune and endocrinologic disorders and diabetes, when implementing medical nutrition therapy (MNT). Identification of all nutritional issues is optimal to integrate MNT for individuals with CD into overall disease management.

Consensus, Imperative

Recommendation Strength Rationale

- The ADA Celiac Disease Work Group concurs with the National Institutes of Health Consensus Development Conference Statement.

CD Inclusion of Gluten-Free Oats

CD Inclusion of Gluten-Free Oats

The RD should advise individuals with CD who enjoy and can tolerate gluten-free oats to gradually include them in their gluten-free dietary pattern. Research on individuals with CD reports that incorporating oats uncontaminated with wheat, barley or rye at intake levels of approximately 50 g dry oats per day is generally safe and improves compliance with the gluten-free dietary pattern.

Fair, Conditional

Recommendation Strength Rationale

- Conclusion statement was **Grade II**

CD Meeting Nutritional Needs

CD: Consumption of Whole/Enriched Gluten-Free Grains and Products

The RD should advise individuals with CD to consume whole or enriched gluten-free grains and products such as brown rice, wild rice, buckwheat, quinoa, amaranth, millet, sorghum, teff, etc. Research reports that adherence to the gluten-free dietary pattern may result in a diet that is low in carbohydrates, iron, folate, niacin, zinc and fiber.

Strong, Imperative

CD: Addition of Multivitamin and Mineral Supplement

If usual food intake shows nutritional inadequacies that cannot be alleviated through improved eating habits, the RD should advise individuals with CD to consume a daily gluten-free age- and sex-specific multivitamin and mineral supplement. Research reports that adherence to the gluten-free dietary pattern may result in a diet that is low in iron, folate, niacin, vitamin B_{12}, calcium, phosphorus and zinc.

Strong, Conditional

Recommendation Strength Rationale

- Conclusion statements were **Grade II**

CD Calcium/Vitamin D for Reduced Bone Density

CD: Calcium/Vitamin D for Reduced Bone Density

For adults with reduced bone density or reduced serum levels of 25-hydroxyvitamin D, the RD should advise the consumption of additional calcium and vitamin D through food or gluten-free supplements. Studies in adults with untreated CD have shown that a gluten-free dietary pattern improves, but may not normalize bone mineral density.

Strong, Conditional

Recommendation Strength Rationale

- Conclusion statement **was Grade I**
- The ADA Celiac Disease Work Group concurs with the National Osteoporosis Foundation Clinician's Guide to Prevention and Treatment of Osteoporosis.

CD Iron Supplementation for Iron Deficiency Anemia

CD: Iron Supplementation for Iron Deficiency Anemia

For individuals with iron deficiency anemia and CD, the RD should advise the consumption of a daily gluten-free multivitamin with iron or additional individualized therapeutic doses of iron. Studies report that iron supplementation may be necessary to achieve normal values of hematological parameters.

Strong, Conditional

Recommendation Strength Rationale

- Conclusion statement **was Grade II**

CD Gluten-Free Dietary Pattern

CD: Gluten-Free Dietary Pattern

The RD should advise and educate individuals with CD to be compliant with a gluten-free dietary pattern. Research on individuals with CD reports that long-term compliance with a gluten-free dietary pattern improves outcomes related to bone density, iron deficiency anemia, villous atrophy, gastrointestinal and neurological symptoms, pregnancy outcomes and quality of life.

Strong, Imperative

Recommendation Strength Rationale

- Conclusion statements were **Grades I andÂ II**

CD Provide Resources and Education on Label Reading

CD: Provide Resources and Education on Label Reading

The RD should provide resources and educate individuals with CD about reviewing the ingredients on labels of food and supplements, using current publications, including those from the United States Food and Drug Administration, for identification and avoidance of sources of gluten, namely wheat, rye, barley, malt and oats (unless oats are gluten-free). Education about the disease is optimal to integrate MNT for individuals with CD into overall disease management.

Consensus, Imperative

Recommendation Strength Rationale

- The ADA Celiac Disease Work Group Concurs with the National Institutes of Health Consensus Development Conference Statement.

CD Education on Food Cross-Contamination

CD: Education on Food Cross-Contamination

The RD should educate individuals with CD regarding cross-contamination in gluten-free food preparation within manufacturing plants, restaurants and home kitchens. Education about the disease is optimal to integrate MNT for individuals with CD into overall disease management.

Consensus, Imperative

Recommendation Strength Rationale

- The ADA Celiac Disease Work Group concurs with the National Institutes of Health Consensus Development Conference Statement.

CD Coordination of Care

CD: Coordination of Care

The RD should implement MNT and coordinate nutrition care with a team of clinical professionals. Depending on the coexisting conditions of the individual with CD, consultation with gastroenterologists, endocrinologists, allergists, dermatologists, hepatologists, pharmacists, social workers, etc., may be warranted. An interdisciplinary team approach is optimal to integrate MNT for individuals with CD into overall disease management.

Consensus, Imperative

Recommendation Strength Rationale

- The ADA Celiac Disease Work Group concurs with the National Institutes of Health Consensus Panel.

CD Monitoring and Evaluation of Dietary Compliance

CD: Monitoring and Evaluation of Dietary Compliance

The RD should monitor the following to evaluate dietary compliance:

- Gluten-free dietary pattern
- Antibody levels
- Potential exposure to cross-contamination
- Hidden sources of gluten in foods, medications and supplements
- Intake of gluten may result in gastrointestinal symptoms, malabsorption and villous atrophy

Strong, Imperative

Recommendation Strength Rationale

- Conclusion statementsÂ were **Grade II**

CD Monitoring and Evaluation of Factors Affecting Quality of Life

CD: Monitoring and Evaluation of Factors Affecting Quality of Life

The RD, at every encounter, should monitor and evaluate the factors affecting the quality of life of individuals with CD, reviewing changes in client status, which includes medical status (e.g., gastrointestinal, immune, neurological and psychological) and social status (e.g., socioeconomic factors, religion, social and medical support and daily stress level). Individuals with CD may not attain the same level of quality of life as the general population, due to social inconveniences of following a gluten-free dietary pattern.

Strong, Imperative

Recommendation Strength Rationale

- Conclusion statements were **Grades I andÂ II**

CD Monitoring and Evaluation of Gastrointestinal Symptoms

CD: Monitoring and Evaluation of Gastrointestinal Symptoms

The RD, after ruling out gluten exposure, should monitor and evaluate persistent gastrointestinal symptoms in individuals with CD, such as bloating, gas, constipation and diarrhea, as there may be other potential causes, such as leaky gut, lactose, fructose and carbohydrate intolerances, bacterial overgrowth, refractory sprue, related cancers, and other gastrointestinal diseases and conditions. Several studies have reported that people with CD (treated and untreated) are more likely to experience gastrointestinal symptoms than healthy controls; compliance with a gluten-free diet reduces but may not eliminate these symptoms.

Fair, Imperative

Recommendation Strength Rationale

- Conclusion statementÂ was **Grade II**

Definitions:

Conditional versus Imperative Recommendations

Recommendations can be worded as ***conditional*** or ***imperative*** statements. Conditional statements clearly define a specific situation, while imperative statements are broadly applicable to the target population without restraints on their pertinence. More specifically, a conditional recommendation can be stated in if/then terminology (e.g., if an individual does not eat food sources of omega-3 fatty acids, then 1 g of EPA and DHA omega-3 fatty acid supplements may be recommended for secondary prevention).

In contrast, imperative recommendations "require," or "must," or "should achieve certain goals," but do not contain conditional text that would limit their applicability to specified circumstances. (e.g., portion control should be included as part of a comprehensive weight management program. Portion control at meals and snacks results in reduced energy intake and weight loss).

Level of Evidence

Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert Opinion Only	Grade Grade Assigna
Quality • Scientific rigor/validity • Considers	Studies of strong design for question Free from	Studies of strong design for question with minor methodological	Studies of weak design for answering the question	No studies available Conclusion based on usual	No evidence that pertains question

Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert Opinion Only	Grade Grade Assigna
design and execution	design flaws, bias and execution problems	concerns OR Only studies of weaker study design for question	OR Inconclusive findings due to design flaws, bias or execution problems	practice, expert consensus, clinical experience, opinion, or extrapolation from basic research	being addresse
Consistency Of findings across studies	Findings generally consistent in direction and size of effect or degree of association, and statistical significance with minor exceptions at most	Inconsistency among results of studies with strong design OR Consistency with minor exceptions across studies of weaker designs	Unexplained inconsistency among results from different studies OR Single study unconfirmed by other studies	Conclusion supported solely by statements of informed nutrition or medical commentators	NA
Quantity • Number of studies • Number of subjects in studies	One to several good quality studies Large number of subjects studies Studies with negative results having sufficiently large sample size for adequate statistical power	Several studies by independent investigators Doubts about adequacy of sample size to avoid Type I and Type II error	Limited number of studies Low number of subjects studies and/or inadequate sample size within studies	Unsubstantiated by published studies	Relevan studies have no been do
Clinical Impact • Importance of studies outcomes • Magnitude of	Studied outcome relates directly to the question	Some doubt about the statistical or clinical significance of effect	Studies outcome is an intermediate outcome or surrogate for the true	Objective data unavailable	Indicate area for future research

Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert Opinion Only	Grade Grade Assigna
effect	Size of effect is clinically meaningful Significant (statistical) difference is large		outcome of interest OR Size of effect is small or lacks statistical and/or clinical significance		
Generalizability To population of interest	Studied population, intervention and outcomes are free from serious doubts about generalizability	Minor doubts about generalizability	Serious doubts about generalizability due to narrow or different study population, intervention or outcomes studied	Generalizability limited to scope of experience	NA

This grading system was based on the grading system from: *Greer N, Mosser G, Logan G, Wagstrom Halaas G. A practical approach to evidence grading. Jt Comm. J Qual Improv. 2000; 26:700-712*. In September 2004, The ADA Research Committee modified the grading system to this current version.

Criteria for Recommendation Rating

Statement Rating	Definition	Implication for Practice
Strong	A **Strong** recommendation means that the workgroup believes that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation), and that the quality of the supporting evidence is excellent/good (grade I or II)*. In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the	Practitioners should follow a **Strong** recommendation unless a clear and compelling rationale for an alternative approach is present.

Statement Rating	Definition	Implication for Practice
	harms.	
Fair	A **Fair** recommendation means that the workgroup believes that the benefits exceed the harms (or that the harms clearly exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade II or III)*. In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Practitioners should generally follow a **Fair** recommendation but remain alert to new information and be sensitive to patient preferences.
Weak	A **Weak** recommendation means that the quality of evidence that exists is suspect or that well-done studies (grade I, II, or III)* show little clear advantage to one approach versus another.	Practitioners should be cautious in deciding whether to follow a recommendation classified as **Weak**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.
Consensus	A **Consensus** recommendation means that Expert opinion (grade IV)* supports the guideline recommendation even though the available scientific evidence did not present consistent results, or controlled trials were lacking.	Practitioners should be flexible in deciding whether to follow a recommendation classified **Consensus**, although they may set boundaries on alternatives. Patient preference should have a substantial influencing role.
Insufficient Evidence	An **Insufficient Evidence** recommendation means that there is both a lack of pertinent evidence (grade V)* and/or an unclear balance between benefits and harms.	Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Insufficient Evidence** and should exercise judgment and be alert to emerging publications that report evidence that clarifies the balance of benefit versus harm. Patient preference should have a substantial influencing role.

*Conclusion statements are assigned a grade based on the strength of the evidence. Grade I is good; grade II, fair; grade III, limited; grade IV signifies expert opinion only and grade V indicates that a grade is not assignable because there is no evidence to support or refute the conclusion. The evidence and these grades are considered when assigning a rating (Strong, Fair, Weak, Consensus, Insufficient Evidence - see chart above) to a recommendation.

Adapted by the American Dietetic Association from the American Academy of Pediatrics, Classifying Recommendations for Clinical Practice Guideline, Pediatrics. 2004;114;874-877.

CLINICAL ALGORITHM(S)

AlgorithmsÂ are provided in the original guideline document for:

- Celiac Disease (CD) Nutrition Guideline
- CD Nutrition Assessment
- CD Nutrition Diagnosis
- CD Nutrition Intervention
- CD Nutrition Monitoring and Evaluation

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

The guideline contains conclusion statements that are supported by evidence summaries and evidence worksheets. These resources summarize the important studies (randomized controlled trials [RCTs], clinical trials, observational studies, cohort and case-control studies) pertaining to the conclusion statement and provide the study details.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- A primary goal of implementing these recommendations is to provide medical nutrition therapy (MNT) guidelines for celiac disease to promote optimal health, prevent and treat malabsorption/malnutrition and other comorbidities and improve quality of life. Potential benefits include a person's ability to achieve optimal nutrition.
- Although costs of MNT sessions and reimbursement vary, MNT is essential for improved outcomes. MNT education can be considered cost effective when considering the benefits of nutrition interventions on the onset and progression of comorbidities versus the cost of the intervention.
- Dietetic practitioners, patients, and consumers may make shared decisions about health care choices; if properly communicated and implemented, this guideline can improve care.

POTENTIAL HARMS

Overall Risk/Harm Considerations

When using these recommendations:

- Review the patient´s age, socioeconomic status, cultural issues, health history, and other health conditions.
- Consider referral to other specialties: Allergy and Immunology, Endocrinology, Gastroenterology, Hematology, Neurology, Obstetrics and Gynecology, Pediatrics, Family Practice, Rheumatology.
- Consider referral to a behavioral specialist if psychosocial issues are a concern.
- Consider a referral to social services to assist patients with financial arrangements if economic issues are a concern.
- Use clinical judgment in applying the guidelines when evaluating patients with celiac disease.
- Give careful consideration to the application of these guidelines for patients with significant comorbidities.

In addition to the above, a variety of barriers may hinder the application of these recommendations.

Recommendation-Specific Risks/Harms

Inclusion of Gluten-Free Oats

- In a small number of persons with celiac disease (CD), research reports that oats may cause villous atrophy, an increase in intraepithelial lymphocytes or exacerbate dermatitis herpetiformis.
- The introduction of oats may result in gastrointestinal symptoms such as diarrhea and abdominal discomfort.Â These symptoms may be due to an increase in fiber intake and not a sign of intolerance to oats.

Meeting Nutritional Needs (Addition of Multivitamin and Mineral Supplement)

- Consumption of nutrients exceeding the upper limit of the Dietary Reference Intakes (DRIs) may lead to adverse condition.

Iron Supplementation

- Consumption of iron beyond the tolerable upper intake level (UL) may result in hemochromatosis.

Gluten-Free Dietary Pattern

- Compliance with a gluten-free dietary pattern before confirmed diagnosis of CD may result in inaccurate diagnostic results.

Providing Resources and Education on Label Reading

- Careful attention must be given to label-reading education. Incomplete or absence of detailed label reading education could result in consumption of products that may contain gluten-containing ingredients.
- Individual need to be instructed on continued monitoring of product labels and ingredients, as manufacturers may periodically change ingredients.

- Incomplete implementation ofÂ label-reading education recommendation may result in liability issues.

Education on Cross-Contamination

- Careful attention must be given to education on cross-contamination to help prevent individuals withÂ CD from unintentionally consuming gluten.

CONTRAINDICATIONS

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- Clinical judgment is crucial in the application of these guidelines. Careful consideration should be given to the application of these guidelines for patients with significant medical co-morbidities.
- Bone density screening may be contraindicated in pregnancy.
- The Consumption of Whole/Enriched Gluten-Free Grains and Products recommendation may be contraindicated in individuals who are on a fiber-restricted diet.

QUALIFYING STATEMENTS

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- This American Dietetic Association Evidence-Based Nutrition Practice Guideline is meant to serve as a general framework for handling clients with particular health problems. It may not always be appropriate to use these nutrition practice guidelines to manage clients because individual circumstances may vary. For example, different treatments may be appropriate for clients who are severely ill or who have co-morbid, socioeconomic, or other complicating conditions. The independent skill and judgment of the health care provider must always dictate treatment decisions. These nutrition practice guidelines are provided with the express understanding that they do not establish or specify particular standards of care, whether legal, medical, or other.
- Evidence-based nutrition practice guidelines are developed to help dietetic practitioners, patients and consumers make shared decisions about health care choices in specific clinical circumstances. If properly developed, communicated and implemented, guidelines can improve care. While they represent a statement of best practice based on the latest available evidence at the time of publishing, they are not intended to overrule professional judgment. Rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance.
- This guideline recognizes the role of patient preferences for possible outcomes of care, when the appropriateness of a clinical intervention involves a substantial element of personal choice or values.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

This publication ofÂ this guideline is an integral part of plans for disseminating the American Dietetic Association Medical Nutrition Therapy (ADA MNT) evidence-based recommendations to all dietetics practitioners. National implementation workshops at various sites around the country and during the ADA Food Nutrition Conference Expo (FNCE) are planned. Additionally, there are recommended dissemination and adoption strategies for local use of the ADA Celiac Disease Evidence-Based Nutrition Practice Guideline.

The guideline development team recommended multi-faceted strategies to disseminate the guideline and encourage its implementation. Management support and learning through social influence are likely to be effective in implementing guidelines in dietetic practice. However, additional interventions may be needed to achieve real change in practice routines.

Implementation of the Celiac Disease Evidence-Based Nutrition Practice Guideline will be achieved by announcement at professional events, presentations and training. Some strategies include:

- **National and Local Events** - State dietetic association meetings and media coverage will help launch the guideline
- **Local Feedback Adaptation** - Presentation by members of the work group at peer review meetings and opportunities for continuing education units (CEUs) for courses completed
- **Education Initiatives** - The guideline and supplementary resources will be freely available for use in the education and training of dietetic interns and students in approved Commission on Accreditation of Dietetics Education (CADE) programs
- **Resources** - Expert members of the guideline team will prepare articles for publications. Materials will be provided that include PowerPoint presentations, full guidelines and pre-prepared case studies. Establishment of a Peer Network is also planned
- **Practical Tools** - Some of the tools that will be developed to help implement the guideline include specially designed resources, such as clinical algorithms, slide presentations, training and toolkits

Specific distribution strategies include:

Publication in full: The guideline is available electronically at the ADA Evidence Analysis Library Web site www.adaevidencelibrary.comÂ and announced to all ADA Dietetic Practice Groups. The ADA Evidence Analysis Library will also provide downloadable supporting information and links to relevant position papers.

IMPLEMENTATION TOOLS

Clinical Algorithm
Slide Presentation

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Dietetic Association (ADA). Celiac disease (CD). Evidence based nutrition practice guideline. Chicago (IL): American Dietetic Association (ADA); 2009. Various p. [341 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2009

GUIDELINE DEVELOPER(S)

American Dietetic Association - Professional Association

SOURCE(S) OF FUNDING

American Dietetic Association

GUIDELINE COMMITTEE

Expert Work Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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In the interest of full disclosure, American Dietetic Association (ADA) has adopted the policy of revealing relationships workgroup members have with companies that sell products or services that are relevant to this topic. Workgroup members are required to disclose potential conflicts of interest by completing the ADA Conflict of Interest Form. It should not be assumed that these financial interests will have an adverse impact on the content, but they are noted here to fully inform readers. Users of the evidence analysis library may assume that only work group members listed below have potential conflicts of interest to disclose.

None of the work group members listed above disclosed potential conflicts of interest.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available to members from the American Dietetic Association Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Executive summary of recommendations. Chicago (IL): American Dietetic Association; 2009. Electronic copies: Available from the American Dietetic Association Web site.
- American Dietetic Association celiac disease evidence-based nutrition practice guideline. Slide set. Chicago (IL): American Dietetic Association; 2009. Electronic copies: Available for purchaseÂ from the American Dietetic Association Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on February 10, 2010. The information was verified by the guideline developer on March 9, 2010.

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When modifying the guidelines for local circumstances, significant departures from these comprehensive guidelines should be fully documented and the reasons for the differences explicitly detailed.

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